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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,096	12/18/2001	Marian L. Kruzel	FDI004	3500

7590 01/31/2006

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EXAMINER	
GUCKER, STEPHEN	
ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,096	KRUZEL, MARIAN L.	
	Examiner	Art Unit	
	Stephen Gucker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Methods using bovine lactoferrin were not contemplated in the Application as originally filed. The Examiner believes that the specification is silent in regards to the structure, properties, and methods of use of bovine lactoferrin. The instant Application is clearly and explicitly drawn to the structure, properties, and methods of use of human lactoferrin. This is a new matter rejection.

5. Because claims 1-7 are now limited by the amendment filed 11/8/05 to methods of use of either bovine or human lactoferrin, the prior art rejections from the last Office Action (filed 6/9/20) that employed Batish as a primary reference are being withdrawn, as Batish disclosed the properties of buffalo lactoferrin, but such rejections could be re-

instated if the instant claims once again encompassed methods of use of buffalo lactoferrin should the instant claims again be amended by a Request for Continued Examination filing (RCE filing) to encompass methods using lactoferrin from any animal species. Applicant is cautioned not to expand the scope of the instant claims in an after-final amendment filing, as such alterations in scope could provide grounds for denying the entry of the after-final amendment.

6. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chander et al. ("Chander") in view of Dickson et al. ("Dickson") for reasons of record and the following. Chander teaches that lactoferrin, including bovine, inhibits the growth of a variety of pathogenic and nonpathogenic micro-organisms such as *E. coli*, *Bacillus subtilus*, *Salmonella typhi*, *Vibrio cholerae*, *Shigella dysentriae*, *Klebsiella pneumoniae*, and *Staphylococcus aureus* both *in vitro* and *in vivo* (pages 417-418). Chander does not disclose that these micro-organisms could contaminate a meat product. Dickson does disclose that *Bacillus subtilus*, *E. coli*, *Staphylococcus aureus*, and *Salmonella typhimurium* do contaminate meat surfaces (abstract and pages 834-835) because of their attachment to lean muscle and fat due to the pathogens' hydrophobicity and surface charges. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use lactoferrin to reduce microbial contamination of meat products because Chander teaches that lactoferrin is effective against the same multiple variety of pathogenic and nonpathogenic micro-organisms that Dickson teaches contaminate meat surfaces by their hydrophobicity and surface charges. The economic and public health desire to reduce microbial contamination by using a compound that is

already known to be effective against the same microbes that are already known to attach or stick to the surface of meat carcasses (such as the germs that cause *E.coli* or salmonella food poisoning) renders the instant claims *prima facie* obvious. Because lactoferrin is a solid protein in its natural state (i.e. when completely 100% pure and separated from water, lactoferrin is a solid, not a liquid or a gas), the growth medium (page 418) used by Chander to dissolve the lactoferrin in meets the limitations of both a carrier and a nutritionally acceptable carrier as the assay medium is comprised of nutrients acceptable to microorganisms. It would also be *prima facie* obvious to dissolve the lactoferrin in other nutritionally acceptable carriers before applying it to a food product intended for human consumption such as meat. Finally, the amino acid sequence of lactoferrin is identically the same whether it is produced recombinantly or isolated from its natural source, so the product-by-process type of limitation recited in the instant claims of "recombinantly produced lactoferrin" does not bestow any patentable distinction to the lactoferrin used in the instant invention, absent any evidence to the contrary.

7. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chander et al. ("Chander") in view of Stiles et al. ("Stiles") for reasons of record and the following. The teachings of Chander are as set forth in **¶6** above. Stiles discloses that *E.coli* and *Klebsiella pneumoniae* are serious fecal and nonfecal contaminants from the skin or hides of animals during processing (pages 867-868 and 870-871). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use lactoferrin to reduce microbial contamination of meat products because Chander

teaches that lactoferrin is effective against both of these food-borne pathogens that Stiles teaches contaminate meat products at the wholesale and retail level. The economic and public health desire to reduce microbial contamination by using a compound that is already known to be effective against the same microbe that is already known to be present in wholesale and retail meats (such as the germs that cause *E.coli* and *Klebsiella* food poisoning) renders the instant claims *prima facie* obvious. Because lactoferrin is a solid protein in its natural state (i.e. when completely 100% pure and separated from water, lactoferrin is a solid, not a liquid or a gas), the growth medium (page 418) used by Chander to dissolve the lactoferrin in meets the limitations of both a carrier and a nutritionally acceptable carrier as the assay medium is comprised of nutrients acceptable to microorganisms. It would also be *prima facie* obvious to dissolve the lactoferrin in other nutritionally acceptable carriers before applying it to a food product intended for human consumption such as meat. Finally, the amino acid sequence of lactoferrin is identically the same whether it is produced recombinantly or isolated from its natural source, so the product-by-process type of limitation recited in the instant claims of "recombinantly produced lactoferrin" does not bestow any patentable distinction to the lactoferrin used in the instant invention, absent any evidence to the contrary.

8. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chander et al. ("Chander") in view of Ryser et al. ("Ryser") for reasons of record and the following in light of the definitions of "meat" from either Webster's dictionary or *WordNet ® 2.0*. The teachings of Chander are as set forth in **¶6** above. Ryser discloses that

gastroenteritis producing food-borne *E.coli* can be enteropathogenic, enterotoxigenic, enteroinvasive, or colohemorragic, and has long been recognized as responsible for numerous cases of infant and travelers' diarrhea (pages 948-949 and 953). Ryser also discloses that *Vibrio cholerae* which causes cholera is present in crab, shrimp, and oysters (pages 948-949 and 952-953), which meet the definition of "meat" as defined either by Webster's dictionary or *WordNet ® 2.0* (the instant specification does not define "meat product," so the Examiner had to rely on extrinsic sources to determine the metes and bounds of the claims). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use lactoferrin to reduce microbial contamination of meat products because Chander teaches that lactoferrin is effective against both food-borne pathogens that Ryser teaches cause infant and travelers' diarrhea, cholera, and sometimes death, from the consumption of raw or undercooked crab, shrimp, oysters, ground beef and ground beef sandwiches. The economic and public health desire to reduce microbial contamination by using a compound that is already known to be effective against both microbes that are already known to be present in raw or undercooked crab, shrimp, oysters, ground beef and ground beef sandwiches (such as the germs that cause *E.coli* food poisoning and cholera) renders the instant claims *prima facie* obvious. Because lactoferrin is a solid protein in its natural state (i.e. when completely 100% pure and separated from water, lactoferrin is a solid, not a liquid or a gas), the growth medium (page 418) used by Chander to dissolve the lactoferrin in meets the limitations of both a carrier and a nutritionally acceptable carrier as the assay medium is comprised of nutrients acceptable to microorganisms. It would

also be *prima facie* obvious to dissolve the lactoferrin in other nutritionally acceptable carriers before applying it to a food product intended for human consumption such as meat. Finally, the amino acid sequence of lactoferrin is identically the same whether it is produced recombinantly or isolated from its natural source, so the product-by-process type of limitation recited in the instant claims of "recombinantly produced lactoferrin" does not bestow any patentable distinction to the lactoferrin used in the instant invention, absent any evidence to the contrary.

Applicant's arguments filed 11/8/05 have been fully considered but they are not persuasive because Applicant argues that the Examiner is unwittingly engaging in hindsight reconstruction in regards to the Naidu patent (US 6,172,040). This is not persuasive because the Examiner has set forth in the prior art rejections the motivation that one of ordinary skill in the art would have to combine the references in the absence of the Naidu patent. Furthermore, because the Naidu patent discloses methods of using bovine lactoferrin and the instant Application does not explicitly mention bovine lactoferrin in the specification as filed, it may be proffered that the instant Application is unwittingly or unintentionally benefiting from the Naidu's patent disclosure. Concerning Applicant's other arguments, the Examiner has set forth very non-technical, "common sense" suggestions and/or motivations on how and why the references should be combined for the simple purpose of inhibiting meat spoilage and food poisoning, which do not include any reasoning that is exclusive to the Naidu patent. Finally, all proteins, of which lactoferrin is but one, are solid, not liquid or gaseous, when 100% purified. Dissolving proteins in liquids is not an idea that comes from the Naidu patent, but is

mere common sense as lactoferrin is dissolved in milk in its endogenous state in nature (hence the name, lacto-(meaning "lactating")-ferrin. Biochemists normally dissolve proteins in liquid in order to use them. The instant claims do not exclude the use of tissue culture media as a nutritionally acceptable carrier for the lactoferrin, nor would it be non-obvious for the ordinary artisan to dissolve lactoferrin into other carriers encompassed by the claims before applying it to meat for reasons already of record, such as it is common sense to use a carrier that is nutritionally acceptable (as compared to "nutritionally unacceptable"?) in order to apply an additive to a food product such as meat.

9. No claim is allowed.

10. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached at (571) 272-0867. The fax phone number for this Group is currently (571)-273-8300.

SG

Stephen Gucker

January 23, 2006

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER